

Remarks/Arguments:

Claims 3 and 4, presented hereby, are pending.

Claims 1 and 2 are canceled, hereby, without prejudice or disclaimer.

Present claims 3 and 4 correspond to claims 1 and 2, respectively, rewritten to more clearly define the present invention; i.e., the claims are rewritten to address the rejections of record under §101 and §112, second paragraph, as explained below.

Claims 1 and 2 were rejected under 35 USC 101 for allegedly being improper "use" claims. Reconsideration is requested in view of the instant amendment to the claims, above, and to the remarks, as follow.

Each of claims 3 and 4 defines a "method of using urodilatin." Claim 3 recites the active, method step "administering urodilatin to a patient in need thereof."

With respect to rejected claim 2, the statement of rejection is mistaken; claim 2 recites the active method step "adding urodilatin to the peritoneal dialysis of such patients." Notwithstanding the foregoing, and in a good-faith effort to advance prosecution, present claim 4 maintains the active method step recited in claim 2, reformatted to recite the "method of using urodilatin comprising adding urodilatin to the peritoneal dialysate of a patient . . . undergoing dialysis."

Accordingly, the rejection under §101 being overcome, withdrawal of the rejection appears in order.

Claims 1 and 2 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Reconsideration is requested in view of the instant amendment to the claims, above, and to the remarks, as follow.

According to the statement of rejection, claim 1 was unclear in reciting "and/or." Due to reciting "and/or" it is alleged that "it [is] unclear whether the use of urodilatin is capable of BOTH improving residual renal function in patients . . . and for prolonging the dialysis-free intervals in patients . . . or only one or the other" (Office Action, page 2). First of all, in that "and/or" is not found in the present claims, the reason for the alleged lack of clarity – reciting "and/or" – does not appear in the present claims and, so, the rejection is overcome.

Secondly, "and/or" is typically used to indicate *either* ONE *or* BOTH of the recited elements. Accordingly, present claim 3 rewrites claim 1 to read

for one or both of (i) improving residual renal function in the patient before obligatory dialysis and (ii) prolonging the patient's, dialysis-free intervals.

As such, the scope of the claim is unequivocally clear.

Besides reciting "and/or," the rejection under § 112, paragraph 2, is based on claims 1 and 2 allegedly failing to "*set forth any steps* involved in the [claimed] method/process" (Office Action, page 3)(*emphasis in original*). According to the statement of rejection, each of claims 1 and 2 allegedly "is indefinite where it merely recites a use without any active, positive, steps delimiting how this use is actually practiced" (Office Action, page 3). This allegation fails to support the rejection, because "how" the invention is "practiced" is the function of the *specification*, not the claims. *In re Roberts*, 176 USPQ313, 315 (CCPA 1973).

Present claims 3 and 4 do, however, recite a *use* followed by an active, positive, method step; which, also, is in keeping with the interpretation of the claims for examination purposes, i.e., "the claims have been examined as being drawn to methods of use, based on an implied administering step" (Office Action, page 3) (albeit, claim 4 recites an "adding" step).

In view of the foregoing explanation, the rejection under §112, second paragraph, is overcome and, therefore, withdrawal of the rejection appears in order.

Claims 1 and 2 were rejected under 35 USC 102(b) based on each of WO 8806596 (WO '596), US 5,565,428 (Clark), and *Eur J Med Res*, 3, 103-110, 1998 (Meyer). Reconsideration of the rejections under §102(b) is requested.

With respect to the rejection based on WO '596, each of the reference passages cited in the statement of rejection discloses, broadly, merely the use of urodilatin as a diuretic.

In connection with the alleged anticipation based on Clark, and contrary to the corresponding statement of rejection, Clark does *not* teach the use of urodilatin for any purpose, whatsoever, let alone for treating chronic renal insufficiency, as alleged in the statement of rejection. As taught by Clark (Clark, column 11, lines 12-19) (*emphasis added*):

In a further embodiment, depending on the chronic disorder being treated, another drug besides IGF-I or IGFBP is administered in conjunction with the IGF-I. For example, for a renal indication, it may be desirable *to administer* in conjunction with IGF-I other renally active *molecules that promote reabsorption and retention of electrolytes such as*, e.g., atrial natriuretic peptide (ANP), ANP analogs, or any variants thereof with or without receptor activity, *urodilatin*.

In other words, Clark did not teach administering urodilatin but, rather, administering agents that would promote resorption and retention of urodilatin.

With respect to Meyer, the reference merely teaches (page 103): "Clinical trials [using urodilatin (URO)] show promising results for various clinical indications." Moreover, contrary to implications made in the statement of rejection, the reference indicates the possible lack of any therapeutic effect in the prophylactic use of urodilatin for the treatment of acute renal insufficiency (ARF). According to the reference (Meyers, page 107, column 1), analysis of the reported clinical trials "illustrate the difficulties in proving a therapeutic effect of URO in oliguric ARF in this patient collective and may also reflect the problems in proving any pharmacological agent in this clinical setting."

None of the §102(b) rejections can be maintained in that each of the rejections fails to demonstrate that each and every claim limitation, as arranged in the claim, is found in each of the cited references, which showing is necessary to establish anticipation under §102(b). *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ253 (Fed. Cir. 1985).

Rejected claim 1 (and present claim 3) is limited to the use of urodilatin for the effect of improving residual renal function in a patient with chronic renal insufficiency before obligatory dialysis, for prolonging the dialysis-free intervals of the patient, or for achieving both effects. In order to anticipate claim 1, at least one of the alternatively recited limitations must "identically appear" in each of the cited references. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). However, neither one of the statements of rejection show where either one of the claim limitations *identically appears* in the cited reference. Since a limitation on rejected claim 1 (and

present claim 3) is absent from each of the cited references, anticipation based on any of the cited references is *negated*. *Kolster Speedsteel AB v. Crucible Inc.*, 230 USPQ81 (Fed.Cir. 1986).

Rejected claim 2 (and present claim 4) is limited to the use of urodilatin for the effect of improving the clearance of fluid and urinary waste substances into the abdominal cavity in a patient with chronic renal insufficiency. None of the statements of rejection shows where the aforesaid limitation is found in each of the cited references. Therefore, since a limitation on claim 2 (and present claim 4) is absent from each of the cited references, each of the rejections under section 102(b) is negated. *Kolster Speedsteel, supra*. *Jamesbury Corp., supra*. *Gechter, supra*.

For the foregoing reasons, none of the rejections under 35 USC 102(b) can be maintained and, as such, withdrawal of the rejections under §102(b) appears in order.

Claims 1 and 2 were rejected under 35 USC 103(a) as allegedly being unpatentable based on the combined teachings of WO '596, Clark, or Meyer in view of US 5,571,789 (Fluge). Reconsideration is requested.

According to the statement of rejection, the claim limitations absent from each of the cited primary references (as explained above in connection with the §102(b) rejections) would have been an allegedly obvious modification of each of the cited primary references based on the teachings of Fluge. Based on the teachings of the references, as combined in the statement of rejection, allegedly "it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as

evidenced by the references, especially in the absence of evidence to the contrary" (Office Action, page 6). The statement of rejection is incorrect.

Fluge discloses no teaching or suggestion that cures the fatal deficiency in each of the cited primary references as a novelty defeating reference under §102(b), as explained above. Since all the claim limitations must be taught or suggested by the cited prior art to establish *prima facie* obviousness of a claimed invention, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), *prima facie* obviousness of the rejected claims (and the present claims) is not established. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

Moreover, reliance on the (alleged) fact that one skilled in the art "would have had a reasonable expectation of success in producing the claimed invention" fails to establish obviousness under §103(a). Where the practitioner cannot foresee the results, obvious to try "with a reasonable chance of success" does not distinguish over obvious to try as an improper basis for a finding of obviousness under §103(a). *Ex parte Old*, 229 USPQ196 (BPA&I 1985). A *reasonable expectation of success* is only part of what the PTO must demonstrate to support a rejection for obviousness under §103(a): "Both the suggestion and reasonable expectation of success must be founded in the prior art." *In re Vaeck*, 20 USPQ2d 1438, 1441 (Fed. Cir. 1991). Even assuming, arguendo, a reasonable expectation of success, as alleged in the statement of

rejection, is "founded in the prior art," this still fails to support the rejection, because the requisite "suggestion" is not found in the prior art. *Vaeck*.

Moreover, Fluge concerns the use of urodilatin in treating pulmonary and bronchial disease. Increasing the glomular filtration rate of the kidneys concerns only an ancillary aspect, i.e., the occurrence of fewer side effects than "observed with a similar dosage of ANP" (Fluge, column 1, 54-61). Accordingly, the reference would have provided no incentive for one of ordinary skill in the art to modify the teachings of any of the primary references as alleged in the statement of rejection. The passages of the reference relied on in the statement of rejection describe, only in general terms, the well-known effects of urodilatin, i.e., increasing water excretion, sodium, and chloride. This provides no motivation, whatsoever, for using urodilatin in accordance with the rejected (and present) claims.

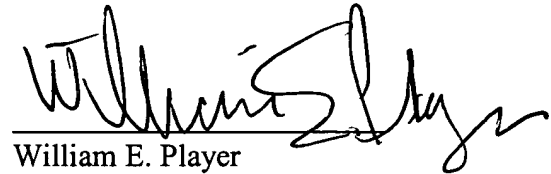
For the foregoing reasons, the rejection under §103(a) cannot be maintained and withdrawal of the rejection appears in order.

Favorable action is requested.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read "William E. Player", written over a horizontal line.

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